

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAUSCH & LOMB INCORPORATED,  
PF CONSUMER HEALTHCARE 1 LLC,

Plaintiffs,

v.

C.A. No. 20-1463-GBW

SBH HOLDINGS LLC,

Defendant.

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**MEMORANDUM ORDER**

Pending before the Court are the following findings and recommendations issued by Magistrate Judge Burke: (1) Report and Recommendation (“R&R”) dated December 29, 2023 (hereinafter, the “Dec. 29 R&R”) (D.I. 102); (2) R&R dated February 8, 2024 (hereinafter, the “Feb. 8 R&R”) (D.I. 108); (3) Oral Order dated April 18, 2024 (hereinafter, the “April 18 Oral Order”) (D.I. 124), and (4) Oral Order dated July 1, 2024 (hereinafter, the “July 1 Oral Order”) (D.I. 141). Defendant SBH Holdings LLC (“Defendant”) filed objections to three of Magistrate Judge Burke’s recommendations (D.I. 111, D.I. 127, D.I. 146), and Plaintiffs Bausch & Lomb Incorporated and PF Consumer Healthcare 1 LLC (“Plaintiffs”) opposed each objection (D.I. 112, D.I. 128, D.I. 147). Having reviewed Magistrate Judge Burke’s recommendations, Defendant’s objections, and all related briefing, the Court hereby finds that Defendant’s objections are **OVERRULED** and Magistrate Judge Burke’s recommendations and orders are **ADOPTED**.

## I. LEGAL STANDARD<sup>1</sup>

The Supreme Court has construed the statutory grant of authority conferred on magistrate judges under 28 U.S.C. § 636 to mean that non-dispositive pretrial matters are governed by § 636(b)(1)(A) and dispositive matters are covered by § 636(b)(1)(B). *Gomez v. United States*, 490 U.S. 858, 873-74 (1989); *see also* Fed. R. Civ. P. 72(a). Pursuant to subparagraph (B), a district court may refer a dispositive motion to a magistrate judge “to conduct hearings, including evidentiary hearings, and to submit to a judge of the court proposed findings of fact and recommendations for the disposition.” 28 U.S.C. § 636(b)(1)(B); *see EEOC v. City of Long Branch*, 866 F.3d 93, 99-100 (3d Cir. 2017). The product of a magistrate judge, following a referral of a dispositive matter, is often called a “report and recommendation.” *Id.* “Parties ‘may serve and file specific written objections to the proposed findings and recommendations’ within 14 days of being served with a copy of the magistrate judge’s report and recommendation.” *Id.* (quoting Fed. R. Civ. P. 72(b)(2)).

“If a party objects timely to a magistrate judge’s report and recommendation, the district court must ‘make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made.’” *EEOC*, 866 F.3d at 99 (quoting 28 U.S.C. § 636(b)(1)). If a party does not object timely to a magistrate judge’s report and recommendation, the party may lose its right to de novo review by the district court. *Id.* However, “because a district court must take some action for a report and recommendation to become a final order and because ‘[t]he authority and the responsibility to make an informed, final determination ... remains with the judge,’ even absent objections to the report and recommendation, a district

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<sup>1</sup> The Court writes for the benefit of the parties who are already familiar with the pertinent background facts.

court should ‘afford some level of review to dispositive legal issues raised by the report.’” *Id.* (internal citations omitted). The district court must give “reasoned consideration” to the report and recommendation. *Id.* at 100.

## **II. DISCUSSION**

### **A. Dec. 29 R&R (D.I. 102) on Defendant’s Motion on JOP:**

On April 4, 2023, Defendant moved for Judgment on the Pleadings (“JOP”) on grounds that United States Patent Nos. 6,660,297 (the “’297 patent”) and 8,603,522 (the “’522 patent” and collectively with the ’297 patent, “the asserted patents”) were invalid as a matter of law. *See generally* D.I. 63. On December 29, 2023, Magistrate Judge Burke determined that Defendant’s arguments should be raised “[a]t some later point in the case[] when the record is fully developed.” *See* D.I. 102 at 7, 11-12. Thus, Magistrate Judge Burke issued the Dec. 29 R&R recommending that Defendant’s Motion for JOP be denied. *Id.* at 12. Neither party objected to the Dec. 29 R&R. Having reviewed the Dec. 29 R&R, Defendant’s Motion for JOP, and all related briefing, the Court agrees that Defendant’s Motion for JOP raised several issues of fact that could not be adjudicated at the Rule 12(c) stage. Accordingly, the Dec. 29 R&R (D.I. 102) denying Defendant’s Motion for JOP is adopted.

### **B. Feb. 8 R&R (D.I. 108) on Claim Construction:**

The parties briefed their positions on claim construction on May 25, 2023. D.I. 79. Of the seven terms briefed for construction, four terms were disputed: (1) “approximately”, in various contexts; (2) “vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof”; (3) “0.04 mg to 40 mg lutein-zeaxanthine combination”; and (4) “early age-related macular degeneration.” *Id.* Magistrate Judge Burke conducted a *Markman* hearing on September 26, 2023 and issued an R&R regarding claim

construction on February 8, 2024. D.I. 108. The Feb. 8 R&R proposed the following constructions:

1. “approximately” with respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and lutein-zeaxanthine combination should be construed to mean “reasonably close to” and “approximately” with respect to the amounts of vitamin A in the form of beta-carotene should be construed to mean “an amount of vitamin A in the form of betacarotene that comes reasonably close to 6 to 10 times the RDA for vitamin A, but not less than 5 times the RDA for vitamin A”

2. “0.04 mg to 40 mg lutein-zeaxanthine combination” should be construed to mean “0.04 mg to 40 mg lutein-zeaxanthine achieved deliberately because of normal composition or through raw material contamination”

3. “vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof” should be construed to mean “lutein, zeaxanthine, or a raw material combination thereof, may be used instead of, or in addition to, vitamin A in the form of beta-carotene”

4. “early age-related macular degeneration” should be construed to mean “early AMD, intermediate AMD, and advanced AMD in one eye only”

*Id.* at 29.

On February 22, 2024, Defendant filed objections to Magistrate Judge Burke’s proposed constructions of two disputed terms, “approximately” and “substituted and supplemented with.”

*See generally* D.I. 111. For the following reasons, Defendant’s objections are overruled, and the Feb. 8 R&R (D.I. 108) on claim construction is adopted.

1. “*approximately*” means “*reasonably close to*.”

The claims of the asserted patents generally disclose compositions and methods of administering compositions which contain “approximately” identified amounts of various ingredients, including vitamin A in the form of beta-carotene, vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine, and/or lutein-zeaxanthine combination. *See, e.g.*, ’522 patent 9:58-67, 10:21-32. The parties addressed the “approximately” terms in two categories: (1) “approximately” (with respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and lutein-zeaxanthine combination), and (2) “approximately” (with respect to the amounts of vitamin A in the form of beta-carotene). D.I. 79 at 7-8. Magistrate Judge Burke agreed that the construction of “approximately” should be addressed in two categories, given that the latter category “was specifically addressed in the context of the ’297 patent reexamination proceedings.” D.I. 108 at 12.

With respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and lutein-zeaxanthine combination, Magistrate Judge Burke found that “approximately” should be given its plain and ordinary meaning of “reasonably close to.” D.I. 108 at 4. Defendant objects to this construction and contends that Magistrate Judge Burke ignored evidence that the patentee disclaimed and disavowed a construction of “approximately” according to its plain and ordinary meaning of “reasonably close to” during prosecution of the ’297 patent. D.I. 111 at 1. Defendant notes, for instance, that the patentee sought to distinguish its claimed composition from several prior art sources during examination proceedings by emphasizing the “unique” and “specific” formulation of its composition. *Id.* According to Defendant, the patentee highlighted “[t]he

specific amounts” of certain formulations and “did not use the word ‘approximately,’” and the Examiner “parroted” the same arguments in its allowance. *Id.* at 2 (arguing that the allowance “[c]onfirm[s] this [was] the [E]xaminer’s reasons for allowance of the ’297 patent”).

However, Magistrate Judge Burke carefully considered each prosecution statement raised by Defendant and correctly found that the statements did not amount to clear and unmistakable disclaimer. D.I. 108 at 8. Magistrate Judge Burke noted, for example, that at several points during prosecution, “the patentee [made] clear that the claimed amounts were approximations.” *Id.* at 9. Because disclaimer “requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable,” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017), the Court agrees that the prosecution history of the ’297 patent does not demonstrate that the patentee unequivocally and unambiguously disavowed the plain meaning of “approximately.”

As Plaintiffs note, two additional tribunals to consider the construction of “approximately” similarly declined to find that the patentee disclaimed the plain meaning of “approximately” during prosecution. D.I. 112 at 3. During reexamination proceedings for the ’297 patent, for instance, the Examiner concluded that the patentee did not “clearly and unambiguously disclaim[] or disavow[] any interpretation of the term ‘approximately’ in order to distinguish the recited ranges of the claimed components from the ranges [in] the prior art.” D.I. 108 (citing D.I. 54, ex. E1 at 8). The United States District Court for the Western District of New York also found that “there [could] be no finding that the disclaimer was made for the purpose of obtaining the ’297 patent.” *See Bausch & Lomb Inc. v. Vitamin Health, Inc.*, 13-CV-6498T, 2015 WL 13574354, at \*7 (W.D.N.Y. Jan. 15, 2015). For these reasons, and for the additional reasons outlined by Magistrate Judge

Burke, Defendant's claims of prosecution history disclaimer are not persuasive. Thus, Defendant's objections are overruled, and the Court adopts the R&R's construction of "approximately."

2. "*substituted*" means "*completely replaced with*"

Magistrate Judge Burke construed the term "vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof," which appears in Claim 19 of the '297 patent and Claim 11 of the '522 patent, to mean "lutein, zeaxanthine, or a raw material combination thereof, may be used instead of, or in addition to, vitamin A in the form of beta-carotene." D.I. 108 at 24. Specifically, Magistrate Judge Burke found that "substituted" should be construed to mean "completely replaced with." *Id.* at 16-17. Defendant objects to this construction of "substituted" and contends that, in construing "substituted" to mean "completely replaced," Magistrate Judge Burke disregarded the prosecution history. D.I. 111 at 1.

Claim construction, however, "begins and ends in all cases with the actual words of the claim." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) (internal citations omitted). Thus, Magistrate Judge Burke began his construction by considering the term "substituted" in light of the plain language of the claims, and Magistrate Judge Burke found that the claim language "align[ed] with Plaintiffs' position." D.I. 108 at 16-17. Because both "substituted" and "supplemented" are used, Magistrate Judge Burke correctly found that the claims present two distinct choices. *Id.* at 16-17; *See, e.g.*, '297 patent, Claim 11 (disclosing vitamin A in the form of beta-carotene that is "substituted *or* supplemented with" certain raw materials). The Court also agrees with Magistrate Judge Burke that Defendant's proposed construction, which construes "substituted" to mean "substituted in part," blurs this distinction and reads "substituted" out of the claim language. D.I. 108 at 16-17. Moreover, as Magistrate Judge Burke explained, the

specifications of the '297 and '522 patents use the terms “supplemented or substituted” consistently with the claims and “do[] not suggest that what is really meant by this phraseology is that lutein, zeaxanthine or lutein-zeaxanthine can only be used to substitute in part beta-carotene (or that at least some amount of beta-carotene must always be included in the composition).” D.I. 108 at 17. Thus, the claim language and the patent specifications support the construction adopted by Magistrate Judge Burke.

Yet, Defendant ignores both the claim language and the specification and instead contends that the prosecution history shows that the patent claims do not permit the total replacement of beta-carotene. D.I. 111 at 6. “[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation,” however, the prosecution history “often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). As illustrated by Magistrate Judge Burke in the Feb. 8 R&R, the prosecution history of the '297 patent proves this point. *See* D.I. 108 at 18-20. Thus, for all of the reasons outlined in the Feb. 8 R&R, Defendant’s objections to the Feb. 8 R&R are overruled, and the Court adopts Magistrate Judge Burke’s construction of the term “substituted” to mean “completely replaced with.”

### 3. *The remaining constructions are also adopted.*

Magistrate Judge Burke also construed “0.04 mg to 40 mg lutein-zeaxanthine combination” to mean “0.04 mg to 40 mg lutein-zeaxanthine achieved deliberately because of normal composition or through raw material contamination” and “early age-related macular degeneration” to mean “early AMD, intermediate AMD, and advanced AMD in one eye only.” D.I. 108 at 29-30. With respect to both terms, Magistrate Judge Burke found that Plaintiffs’ proposals were



supported by the intrinsic and extrinsic evidence. *Id.* at 14-15, 28. Having reviewed the record evidence, the Court agrees with Magistrate Judge Burke's findings and adopts Magistrate Judge Burke's proposed constructions of both terms.

For the reasons discussed above, the Feb. 8 R&R regarding claim construction is adopted in whole, and Defendant's objections are overruled.

**C. April 18 Oral Order (D.I. 124):**

On March 8, 2024, Plaintiffs moved to strike an attorney signed document entitled "SBH's Disclosure/Opinion of Unretained Expert Witness Zac Denning" (hereinafter, the "Denning Disclosure"), provided by Defendant pursuant to Rule 26(a)(2)(c). D.I. 113; D.I. 114 at 1. Plaintiffs also moved to strike any nominal invalidity defenses for which Defendant had not proffered any expert testimony, or alternatively, to preclude Defendant from supplementing expert testimony on those defenses. D.I. 114 at 1. Magistrate Judge Burke issued an Oral Order on April 18, 2024, which granted-in-part and denied-in-part Plaintiff's Motion to Strike. *See* D.I. 124. The Oral Order explained that the Denning Disclosure failed to satisfy the requirements of Rule 26 because it did not provide any facts to support the opinions. *Id.* Thus, the Oral Order granted Plaintiffs' Motion to Strike the Denning Disclosure. *Id.* Plaintiffs' Motion was otherwise denied. *Id.*

On May 1, 2024, Defendant objected to the Oral Order on grounds that the order violated this Court's referring order (D.I. 40), which excluded from referral any Daubert motions and motions in limine. *See generally* D.I. 127. Alternatively, if the Court found that Magistrate Judge Burke had authority to decide the Motion, Defendant asserted that: (1) the Oral Order "was clearly erroneous as the disclosure adequately disclosed a "summary of facts" in compliance with F.R.C.P. 26(a)(2)(C)(ii); and (2) "it was an abuse of discretion to grant the order without leave for defendant

to amend or supplement the disclosure.” *Id.* With respect to Defendant’s argument that Magistrate Judge Burke abused his discretion by failing to grant Defendant leave to amend, Defendant concedes that this is a new argument. D.I. 127 at 7. Because Defendant did not provide good cause for raising this new argument, as required under Paragraph 5 of the Court’s Standing Order, this argument was waived.

As to Defendant’s argument that Magistrate Judge Burke lacked authority to decide the Motion to Strike, this too fails. Plaintiffs moved to strike the Denning Disclosure on grounds that the disclosure failed to comply with Rule 26. D.I. 114 at 1. Thus, the Court agrees with Plaintiff that “[t]he relevant issue is *not* whether Mr. Denning can survive a *Daubert* motion.” D.I. 128 at 3 (emphasis added). Moreover, as parties are authorized pursuant to Rule 37(c)(1) of the Federal Rules of Civil Procedure to strike all or portions of an expert’s report under Rules 26 and 37, the Court finds (consistent with the Oral Order), that Plaintiffs did not mischaracterize a *Daubert* motion as a motion to strike. D.I. 124. Thus, Magistrate Judge Burke had authority to resolve the Motion.

With respect to Defendant’s argument that the Oral Order’s findings were erroneous, Defendant fails to raise any specific deficiencies or flaws with Magistrate Judge Burke’s reasoning. *See* D.I. 127 at 3-5. Instead, Defendant cites to “[t]he Third Circuit[’s] . . . standard of qualifying experts” under F.R.E. 702. *Id.* Yet, as noted *supra*, Plaintiffs’ Motion did not challenge Mr. Denning’s qualifications to testify as an expert. Nor did the Oral Order resolve the Motion under Rule 702. Thus, Rule 702 is irrelevant. Finally, like Magistrate Judge Burke, the Court finds that the Denning Disclosure could not satisfy the “summary of facts and opinions” standard of Rule 26 by asserting conclusory statements regarding: (1) the “substituted or supplemented with” term in claim 19 of the ’297 patent and claim 11 of the ’522 patent, (2) Mr. Denning’s

employment history, and (3) Mr. Denning's conclusory opinions on the indefiniteness and enablement defenses. D.I. 124.

For these reasons, Defendant's objections to the April 18 Oral Order (D.I. 124) are overruled.

**D. July 1 Oral Order (D.I. 141):**

Shortly following Magistrate Judge Burke's April 18 Oral Order striking the Denning Declaration, D.I. 124, Defendant served the Reply Report of SBH Unretained Expert Zac Denning (the "Denning Reply Report") on April 26, 2024. D.I. 135 at 1. Plaintiffs subsequently moved to strike the Denning Reply Report on grounds that the Denning Reply Report violates the Court's Scheduling Order. D.I. 134 at 1. Magistrate Judge Burke agreed and, on July 1, 2024, granted Plaintiff's Motion to Strike the Denning Reply Report. *See generally* D.I. 141. The Oral Order explained that "[p]aragraph 7(f)(i) of the [Scheduling Order] is clearly meant to permit an expert to file a reply expert report only if an expert for that side has previously properly submitted an opening/initial expert report or disclosure on the subject at issue." *Id.* Additionally, because the April 18 Oral Order struck the Denning Disclosure, the Oral Order found "no valid initial expert report/disclosure having been served by Mr. Denning or any other expert for Defendant as to the subject matter at issue in Mr. Denning's reply report." *Id.* Thus, Magistrate Judge Burke granted Plaintiffs' Motion to Strike the Denning Reply Report. *Id.*

On July 12, 2024, Defendant objected to the Oral Order on grounds that Magistrate Judge Burke lacked authority to resolve Daubert motions and motions in limine. *See generally* D.I. 146. However, consistent with the Court's holding with respect to the Denning Disclosure, the Court finds that Magistrate Judge Burke was within his authority to resolve the Motion to Strike. As Plaintiffs note, the Motion to Strike "was not based on whether Mr. Denning's proposed testimony

can survive a challenge under Daubert, nor was it a trial motion.” D.I. 147 at 3. Rather, Plaintiffs moved to strike the Denning Reply Report on grounds that the report violated the Court’s Scheduling Order. *Id.* Because the Court’s Referral Order referred “all pre-trial matters up to and including expert discovery matters,” Magistrate Judge Burke was authorized to resolve the Motion to Strike. *See* D.I. 40.

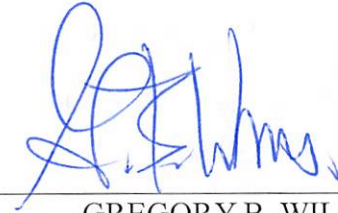
Defendant next contends that the Oral Order “was clearly erroneous” because the Denning Reply Report was “timely and properly submitted in full compliance with the scheduling order.” D.I. 146 at 4. The Court disagrees. As the Oral Order explained, Defendant had no valid initial report for Mr. Denning following the April 18 Oral Order. D.I. 141. Thus, to serve the Denning Reply Report pursuant to the Court’s Scheduling Order, the Court agrees with Magistrate Judge Burke that Defendant was required to serve the Denning Reply Report on or before the deadline for opening expert disclosures. *Id.* Because Defendant failed to do so, there is no dispute that the Denning Reply Report was untimely. Finally, the Court agrees that Defendant failed to demonstrate good cause to permit its violation of the Scheduling Order under Fed. R. Civ. P. 16(b)(4). *Id.* Therefore, Defendant’s objections are overruled.

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At Wilmington, this 27th day of September 2024, **IT IS HEREBY ORDERED** that:

1. The Report and Recommendation dated December 29, 2023, D.I. 102, is **ADOPTED**, and Defendant’s Motion for Judgment on the Pleadings, D.I. 63, is **DENIED**.
2. The R&R dated February 8, 2024, D.I. 108, is **ADOPTED**, and Defendant’s objections, D.I. 111, are **OVERRULED**.

3. The Oral Order dated April 18, 2024, D.I. 124, is **ADOPTED**, and Defendant's objections, D.I. 127, are **OVERRULED**.
4. The Oral Order dated July 1, 2024, D.I. 141, is **ADOPTED**, and Defendant's objections, D.I. 146, are **OVERRULED**.



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GREGORY B. WILLIAMS  
UNITED STATES DISTRICT JUDGE